

Declaration of Conformity

Manufacturer: **Changzhou Chuangjia Medical Appliance Co., Ltd.**
Sanhekou Development Zone, Zhenglu Town213115, Changzhou, PEOPLE'S
REPUBLIC OF CHINA

European Representative: **Lotus NL B.V.**
Koningin Julianaplein 10, 1 e Verd,
2595AA, The Hague, The Netherlands.

Product Name **Intravenous Needles for Singel Use**

Model Number: **0.4, 0.45, 0.5 ,0.55, 0.6, 0.7, 0.8, 0.9, 1.1, 1.2**

UMDNS Code: **12748**

Classification (MDD, Annex IX): **Ila, rule 7**

Conformity Assessment Route: **Annex V**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany

Identification number: **CE** 0123

(EC) Certificate(s): G2 076830 0008 Rev.02

Expire date of the Certificate: 2024-05-26

Place, Date of Issue: **Changzhou, 2021-03-19**

Signature: _____

Name: **Mr. Jia Xu**

Position: **General Manager**

